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EXAMINER	
LU, FRANK WEI MIN	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/886,779	SABANAYAGAM ET AL.	
	Examiner	Art Unit	
	FRANK W. LU	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 23-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11 and 23-38* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE filed on October 25, 2007 and the amendment filed on February 1, 2008 have been entered. The claims pending in this application are claims 11 and 23-38. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of applicant's amendment filed on February 1, 2008.

Claim Objections

2. Claims 32 and 33 are objected to because of the following informality: "a same" should be "the same". Note that applicant does not address this issue.

3. Claim 34 is objected to because of the following informality: "claims 11 and 23" should be "claim 11 or 23".

4. Claim 35 is objected to because of the following informality: "claims 25, 26, 27, 28, and 29" should be "claim 25, 26, 27, 28, or 29".

5. Claim 36 is objected to because of the following informality: "claims 30, 31, 32, and 33" should be "claim 30, 31, 32, or 33".

6. Claim 36 or 37 or 38 is objected to because of the following informality: "the sequence of interest along the z coordinate" should be "the unique sequence of interest along the z coordinate".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. New Matter

Claims 11, 24-26, and 30-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The preamble of independent claim 11 contains the limitation "multiple copies of an unique sequence of interest extending in the array's z dimension, wherein each copy has an identical generic oligonucleotide that is attached to the array's x and y coordinates and wherein each copy also carries a unique nucleotide of interest repeated at least two times in the z dimension of the array and wherein between each of the unique sequence of interest there is at least one region that is complementary to at least a portion of the identical generic oligonucleotide attached to the array's x and y coordinates". Although page 10, last paragraph of

the specification describes that "[T]he present invention contemplates solving both problems by utilizing circular nucleic acid in the production of the array. The method contemplates a solid support with positions for oligonucleotides defined by x and y coordinates. At each position *(e.g.,* x1, y1; x1, y2; etc.), a oligonucleotide is immobilized. In one embodiment (see Figure 1A), the same oligonucleotide *(ie.,* an oligonucleotide with the same generic nucleotide sequence) is immobilized in every position (or nearly every position, with some positions left empty or for controls) on the solid support. In this embodiment, a circular DNA template comprising i) a region having a sequence complementary to at least a portion of said generic oligonucleotide (shown in Figure 1A as A_AAACC), and ii) a region comprising a sequence of interest (shown in Figure 1A as QQQQ etc.) is employed. The region having a sequence complementary to at least a portion of said generic oligonucleotide permits hybridization of the circular template to the immobilized oligonucleotide (Figure 1A is merely illustrative and is not meant to limit the sequence or length of the sequence of this hybridizing region; indeed, regions larger than six nucleotides are preferred)", nowhere in page 10, lines 15-29 and page 11, lines 19-23 of the specification suggested by applicant and other parts of the specification describes that each copy has an identical generic oligonucleotide that is attached to the array's x and y coordinates as recited in the preamble of claim 11 because the same oligonucleotide *(ie.,* an oligonucleotide with the same generic nucleotide sequence) in page 10, lines 9-29 is different from multiple copies of an unique sequence of interest extending in the array's z dimension wherein each copy of multiple copies of an unique sequence of interest also carries a unique nucleotide of interest repeated at least two times in the z dimension of the array. Furthermore, nowhere in the specification describes at least two copies of each of the unique sequence of interest separated by

a generic nucleic acid sequence in the terminus of each of immobilized oligonucleotides as recited in claim 30.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application". MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 11 and 23-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 11 or 23 or 30 is rejected as vague and indefinite in view of the preamble. Although the claim is directed to an ordered array of immobilized oligonucleotides in the array' s x and y coordinates with multiple copies of a sequence of interest extending in the array' s z dimension, it is unclear whether there is/are one or more of the immobilized oligonucleotides extending in the array' s x or y dimension or not. Please clarify.

12. Claim 11 is rejected as vague and indefinite in view of step (d) because it is unclear what is a growth strand in the claim and the phrase "wherein each extended immobilized oligonucleotide has a position on the array defined by its x and y coordinates, and is extended in

the z dimension, a growing strand, such that each extended immobilized oligonucleotide comprises at least two copies of said unique sequence of interest extending in the z dimension by the circular DNA template having the unique sequence of interest" does not make sense. Please clarify.

13. Claim 11 is rejected as vague and indefinite in view of the preamble of the claim. Since the preamble of the claim requires that between each unique sequence of the interest there is at least one region that is complementary to at least a portion of the identical generic oligonucleotide attached to the array's x and y coordinates and does not require that the at least a portion of the identical generic oligonucleotide is attached to the array defined by x and y coordinates from z coordinate, if at least one region that is fully complementary to at least a portion of the identical generic oligonucleotide attached to the array's x and y coordinates and the identical generic oligonucleotide is attached to the array by a chemical bond from x or y coordinate, multiple copies of a sequence interest extend along either x or y dimension and does not extend along z dimension which is opposite to the claim. Please clarify.

Response to Arguments

In page 10, last paragraph bridging to page 11, first paragraph of applicant's remarks filed on October 25, 2007, applicant argues that "[T]urning to claim 11, the claims are referring to growth in the z direction, which is attached to the strand at its x, y position. The Examiner contends that if the rolling circle is hybridized on the immobilized probe, it will not extend to z dimension but rather to x, y dimension. Applicants refer to the drawings and the specification in whole in responding that this is not the case. In an array, the position of each probe is defined by its location on the: array with x and y coordinates. Each of the probes will thus always extend to

the third dimension, i,e. z dimension. Even the generic part of the probe: will extend to the third dimension, because: the arrays form a three dimensional space for detection (see also, Exhibit A). Therefore, once the rolling, circle attaches to the initial probe attached to the solid surface, it can not go along the array, but must extend outwards when the polymerase extends it".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. Since the preamble of the claim requires that between each unique sequence of the interest there is at least one region that is complementary to at least a portion of the identical generic oligonucleotide attached to the array's x and y coordinates and does not require that the at least a portion of the identical generic oligonucleotide is attached to the array defined by x and y coordinates from z coordinate, if at least one region that is fully complementary to at least a portion of the identical generic oligonucleotide attached to the array's x and y coordinates and the identical generic oligonucleotide is attached to the array by a chemical bond from x or y coordinate, multiple copies of a sequence interest extend along either x or y dimension and does not extend along z dimension which is opposite to the claim.

14. Claim 23 is rejected as vague and indefinite in view of the preamble of the claim. Since the preamble of the claim requires each copy of a sequence of interest contains a different unique sequence and each different sequence is complementary to the sequence of interest, it is unclear why the different unique sequence of the sequence of interest can be complementary to the sequence of interest as recited in the claim. In other word, why the different unique sequence of the sequence of interest in the sequence of interest can be complementary to itself. Please clarify.

Response to Arguments

In page 11, second paragraph of applicant's remarks filed on October 25, 2007, applicant argues "[T]urning to claim 23. The claim refers to multiple sequences of interest which are different from each other. This is clearly described in the specification, at pages 10-11. Applicants describe that each probe contains a different sequence of interest (see, e, g. p.10, lines, 23-29). The examiner contended that because the claims refer to the different sequences of being complementary to the sequence of interest, the claim is not clear. The basic principle of the method by which the arrays are created is the novel use of rolling circle amplification (RCA). As explained in the specification, and shown in the drawings, such as Figures 1 and 2, the original circle contains the sequence of interest (or its complement). Once this circle hybridizes with the probe attached on the solid surface, a polymerase is used to create at least two linear repeats of the circle thereby making the extended probe a complement of what the circle originally consisted of. The tem 'complement' is a term of art. The skilled artisan understands what the term complement to a target sequence refers to. The claim language is consistent with language understood by one skilled in the art".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. Since the preamble of the claim requires each copy of a sequence of interest contains a different unique sequence and each different sequence is complementary to the sequence of interest, it is unclear why the different unique sequence of the sequence of interest can be complementary to the sequence of interest as recited in the claim. In other word, why the different unique sequence of the sequence of interest in the sequence of interest can be complementary to itself.

15. Claim 23 is rejected as vague and indefinite in view of d) of the claim because it is unclear what is a growth strand in the claim and the phrase "wherein each extended immobilized oligonucleotide has a position on the array defined by its x and y coordinates, and is extended in the z dimension such that each extended immobilized oligonucleotide comprises at least two copies extending at the terminus in the direction of the z dimension, a growing strand, of the sequence of interest contained in said hybridized circular template by a circular DNA template having an unique sequence of interest" does not make sense. Please clarify.

16. Claim 30 is rejected as vague and indefinite because it is unclear that the terminus is the terminus of what. Please clarify.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

18. Claims 30-33 and 36-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith *et al.,* (US Patent No. 5,753,439, filed on May 19, 2003).

Smith et al., teach arrays of probes. Each probe in the array comprises a constant 5'-region, a constant 3'-region and a variable internal region wherein the variable region comprised one or more repeat sequences. The repeat sequences comprise heterologous or homologous sequences which are variable in length or base sequences. Sequences contain purine

or pyrimidine bases or neutral bases such as inosine. Either the nucleic acids or the probes of the array are labeled with a detectable label or fixed to a solid support. Probes are single-stranded or partly single-stranded and partly double-stranded. Arrays comprise between about 10 to about 10,000 different probes (see column 9, lines 18-34). In certain situation, the repeat sequences are about 2 to about 2000 (see column 15, claims 1 and 2).

Regarding claim 30, claim 30 is directed an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest along the z coordinate wherein the at least two copies of the unique sequence of interest are separated by at least one generic nucleic acid sequence and each unique sequence of interest is different in each extended immobilized oligonucleotide. Since Smith *et al.,* teach an array comprising 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence (see column 9, lines 18-34 and column 15, claims 1 and 2) and claim 30 does not require that the unique sequence of interest is different from the generic nucleic acid sequence, Smith *et al.*, teach an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide (ie., each of 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence) comprises at least two copies of the unique sequence of interest (ie., some repeats from 2000 repeats) wherein the at least two copies of the unique sequence of interest (ie., some repeats from 2000 repeats) are separated by at least one generic nucleic acid sequence (ie., other repeats from 2000 repeats) and each the unique sequence of interest is different in each extended immobilized oligonucleotide (ie., since one repeat taught by Smith *et*

al., is considered as an unique sequence of interest in one of the extended immobilized oligonucleotide while three repeats taught by Smith *et al.*, is considered as an unique sequence of interest in another of the extended immobilized oligonucleotide, the unique sequence of interest in one of the extended immobilized oligonucleotide is different from the unique sequence of interest in another of the extended immobilized oligonucleotide). The probes on the array taught by Smith *et al.*, are considered to be along the Z coordinate since each of these probes from one end to another end has 5' to 3' direction and the array itself is a three dimension structure. Furthermore, applicant has no evidence to indicate that these probes on the array taught by Smith *et al.*, are not along the Z coordinate. Since the phrase "at least two copies of each of the unique sequence of interest separated by a generic nucleic acid sequence in the terminus extending to the direction of the z-dimension" is read as that a generic nucleic acid sequence in the terminus of each of the immobilized oligonucleotide extending to the direction of the z-dimension is between at least two copies of each of the unique sequence of interest, the phrase "the terminus" in the claim is not equal to 5' or 3' terminus of the immobilized oligonucleotide but is a region near 5' or 3' terminus of the immobilized oligonucleotide. Since claim 30 does not require that the unique sequence of interest is different from the generic nucleic acid sequence, Smith *et al.*, teach at least two copies of each of the unique sequence of interest (ie., two repeats near 3' terminus of the probe taught by Smith *et al.*,) separated by a generic nucleic acid sequence (ie., one repeat near 3' terminus of the probe taught by Smith *et al.*,) in the terminus (ie., a region near 3' terminus of the probe taught by Smith *et al.*,) extending to the direction of the z-dimension.

Regarding 31-33, since these different probes taught by Smith *et al.*, have 2-2000 repeats (see column 9, lines 18-34 and column 15, claims 1 and 2), Smith *et al.*, disclose that each extended immobilized oligonucleotide comprises at least three copies of said unique sequence of interest (ie., three repeats from 2000 repeats) separated by at least two copies of a generic nucleic acid sequence (ie., other two repeats from 2000 repeats) as recited in claim 31 and each extended immobilized oligonucleotide comprises at least 10 to 50 copies of said unique sequence of interest (ie., 10-50 repeats from 2000 repeats) separated by the same generic nucleic acid sequence (ie., other identical repeats from 2000 repeats) as recited in claim 32 and 33.

Regarding claims 36-38, different probes on the arrays in Figures 6A to 6C taught by Smith *et al.*, have 10-109 repeats wherein 5' and 3' ends of these probes are labeled with biotin and rhodamine respectively. Target nucleic acids comprising 88, 55, and 17 repeats with a fluorescein at their 3' ends are hybridized with an identical array in separate experiments and digested with S1 nuclease. Then strand displacement assays are performed. When the probe contains more internal repeats than the target, the rhodamine label is lost in the strand displacement and the resultant product is red. Similarly, when the target contains more internal repeats than the probe, the fluorescein label is lost and the product is green. When the probe and the target both contain the same number of repeats, both rhodamine and fluorescein remain and the resultant color is yellow (see column 12, example 4, and Figures 6A to 6C). When target nucleic acids comprising 88, 55, and 17 repeats hybridize with their corresponding probes (having 88, 55, and 17 repeats) on the array, the resultant colors must be yellow. Therefore, Smith *et al.*, teach that at least two copies of a fragment of a template nucleic acid (ie., 88, 55, or 17 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeats

of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the unique sequence of interest along the z coordinate as recited in claim 36, at least ten copies of a fragment of a template nucleic acid (ie., 88, 55, or 17 repeats in one of the target nucleic acids) corresponding to the unique sequence of interest (ie, repeats of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the unique sequence of interest along the z coordinate as recited in claim 37, and at least fifty copies of a fragment of a template nucleic acid (ie., 88 or 55 repeats in one of the target nucleic acids) corresponding to the unique sequence of interest (ie, repeat of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the unique sequence of interest along the z coordinate as recited in claim 38.

Therefore, Smith *et al.,* teach all limitations recited in claims 30-33 and 36-38.

Response to Arguments

In page 11, sixth paragraph bridging to page 12, third paragraph of applicant's remarks filed on October 25, 2007, applicant argues that "[T]he present claims require a unique sequence at the z-dimension at the end of each probe. This is unlike Smith, where the each probe has an identical sequence at the end of each z-dimension probe. The significant difference between the array of the present invention and the arrays as described in Smith should be clear from the drawing".

These arguments have been fully considered but they are not persuasive toward the withdrawal of the rejection. First, the claims do not require that a unique sequence at the z-dimension at the end of each probe as argued by applicant but only require at least two copies of each of the unique sequence of interest separated by a generic nucleic acid sequence in the

terminus extending to the direction of the z-dimension. Second, since the phrase "at least two copies of each of the unique sequence of interest separated by a generic nucleic acid sequence in the terminus extending to the direction of the z-dimension" is read as that a generic nucleic acid sequence in the terminus of each of the immobilized oligonucleotide extending to the direction of the z-dimension is between at least two copies of each of the unique sequence of interest, the phrase "the terminus" in claim 30 is not equal to 5' or 3' terminus of the immobilized oligonucleotide but is a region near 5' or 3' terminus of the immobilized oligonucleotide. Since claim 30 does not require that the unique sequence of interest is different from the generic nucleic acid sequence, Smith *et al.*, teach at least two copies of each of the unique sequence of interest (ie., two repeats near 3' terminus of the probe taught by Smith *et al.*,) separated by a generic nucleic acid sequence (ie., one repeat near 3' terminus of the probe taught by Smith *et al.*,) in the terminus (ie., a region near 3' terminus of the probe taught by Smith *et al.*,) extending to the direction of the z-dimension.

Conclusion

19. No claim is allowed.

20. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

/Frank W Lu /
Primary Examiner, Art Unit 1634
May 22, 2008

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	09/886,779	SABANAYAGAM ET AL.	
	Examiner	Art Unit	
	FRANK W. LU	1634	